Boston Scientific

Epic™ Vascular

Self-Expanding Stent System

Directions for Use

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Epic™ Vascular

Self-Expanding Stent System

℞ ONLY
Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING
Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

DEVICE DESCRIPTION
The Epic™ Vascular Self-Expanding Stent System (Epic™ Stent System)is comprised of two components: the implantable endoprosthesis and the stent delivery system. The stent is a laser cut self-expanding stent composed of a nickel titanium alloy (Nitinol). On both the proximal and distal ends of the stent, radiopaque markers made of tantalum increase visibility of the stent to aid in placement. The stent is constrained within a 6F (2.1 mm maximum outside diameter) delivery system. The delivery system is a coaxial design with an exterior shaft to protect and constrain the stent prior to deployment. The delivery system is an Over-The-Wire system compatible with 0.035 in (0.89 mm) guidewires.

When ready to be implanted, the stent is deployed by retracting the exterior shaft of the delivery system. A radiopaque marker at the distal end of the delivery system aids in visibility during deployment. As the stent is exposed to body temperature, it expands to appose the vessel wall.

The Epic™ Vascular Self-Expanding Stent System is available in a variety of stent diameters and lengths. The delivery system is also offered in two shaft lengths (75 cm and 120 cm).

Please see the product label for the specific delivery system length, stent diameter, and stent length.

Contents
One (1) Epic™ Vascular Self-Expanding Stent System

INTENDED USE
The Epic™ Vascular Self-Expanding Stent System is intended for the treatment of iliac artery atherosclerotic lesions and obstructions.

INDICATIONS FOR USE

Epic™ Vascular Self-Expanding Stent System is indicated for the improvement of luminal diameter in patients with de novo or restenotic symptomatic atherosclerotic lesions up to 120 mm in length in the common and/or external iliac arteries, with a reference vessel diameter between 5 and 11 mm.

CONTRAINDICATIONS
There are no known contraindications.

WARNINGS

- Only physicians who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects, and hazards commonly associated with interventional procedures should use this device.
- Do not use after the "Use By" date specified on the package. Ensure that the device has been properly stored in a cool, dark, dry place prior to use.
- Do not use if the temperature exposure indicator dot is red.
- Do not use if the temperature exposure indicator dot is missing.
- Stenting across a bifurcation or side branch could compromise future diagnostic or therapeutic procedures.
- Persons allergic to nickel-titanium may suffer an allergic response to this implant.
- Improper stent size selection may lead to stent migration or stent jumping.
- Remove all slack from the catheter prior to stent deployment, as excessive slack may result in stent jumping or the stent length being reduced.
- If unable to initiate release of the stent or if strong resistance is met with the introduction of the delivery system, remove the entire system from the patient and introduce a new system.
- Once the stent is partially deployed, it cannot be "recaptured" or "resheathed" using the stent delivery system.
- As with any type of intravascular implant, infection secondary to contamination of the stent, may lead to thrombosis, pseudoaneurysm, or rupture into a neighboring organ or into the retroperitoneum.
- The stent may cause thrombus or distal emboli to migrate from the site of the implant down the arterial lumen.
- Do not expose to organic solvents (e.g. alcohol).
- The long-term outcome following repeat dilatation of endothelialized stents is unknown at present.
- In patients with poor kidney function, contrast agents may precipitate kidney failure.

PRECAUTIONS

- Safety and effectiveness has not been demonstrated in patients with the following characteristics:
  - Highly calcified lesions resistant to PTA.
  - Persistent, intraluminal thrombus at the target lesion.
  - Uncorrected bleeding disorders or patients who cannot receive anticoagulation or anti-platelet aggregation therapy.
  - Perforated vessels evidenced by extravasation of contrast media.
  - Lesions that are within or adjacent to an aneurysm.
  - Vessels with excessive tortuosity.
- The delivery system is not designed for use with power injection systems.
- Do not use a kinked delivery system.
- Always use an introducer or guide sheath for the implant procedure, to protect the access site.
- Only advance the stent delivery system over a guidewire.
- Never dilate the stent using a balloon that is larger in diameter than the labeled diameter of the stent.
- When catheters are in the body, they should be manipulated only under fluoroscopy. Radiographic equipment that provides high quality images is needed.
- Two stents can be placed to cover a lesion. Should more than one stent be required, allow for at least 5 mm of stent overlap. It is generally recommended that the distal stent be placed first. If stent overlapping is needed, stent materials should be of similar composition.
- The stent delivery system is not intended for arterial blood monitoring.
- Prior to completion of the procedure, utilize fluoroscopy to ensure proper positioning of the stent. If the target lesion is not fully covered, use additional stents as necessary to adequately treat the lesion.
- The minimally acceptable sheath French size is printed on the package label. Do not attempt to pass the stent delivery system through a smaller size sheath introducer than indicated on the label.
- In the event of thrombosis of the expanded stent, thrombolysis and/or PTA should be considered.
- In the event of complications such as infection, pseudoaneurysms or fistula formation, surgical removal of the stent may be required.
- Recrossing a stent with adjunct devices must be performed with caution.
- Premature removal of the safety lock may result in an unintended deployment of the stent.
- Limited data exists on the use of two overlapping stents from the ORION clinical trial.

MAGNETIC RESONANCE IMAGING (MRI)
Non-clinical testing has demonstrated the Epic™ Stent System is MR Conditional. It can be scanned safely up to a total length of 155 mm and overlapping stents up to 155 mm under the following conditions:

- Static magnetic field of 3 Tesla and 1.5 Tesla
- Spatial gradient field of 2500 Gauss/cm
- Normal operating mode only with a maximum whole body (WB) averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of active scanning for patient landmarks above the umbilicus (patient navel).
- Maximum WB-SAR of 1 W/kg for 15 minutes of scanning for patient landmarks below the umbilicus.
- Use whole body transmit/receive coil only. Do not use local transmit coils. Local receive coils can be used.

MRI at 3T or 1.5T may be performed immediately following the implantation of the Epic Stent. The Epic Stent should not migrate in this MRI environment. This stent has not been evaluated to determine if it is MR Conditional beyond these conditions.

Magnetic Resonance Conditional

3.0 Tesla Temperature Information
In non-clinical testing, the Epic Stent at single lengths of 120 mm and overlapped lengths of 155 mm produced a maximum temperature rise of 4.4°C at a maximum whole body averaged of 2 W/kg, that was determined by validated calculation for 15 minutes of MR scanning in a 3 Tesla Siemens Magnetom Trio®, software version Numaris/4, Syngo® MR A30, COEM VD20F, Syngo VE31G, N4 VA30A Latest MR scanner. In this model, the reported temperatures are conservative as they do not take into account the cooling effects of perfusion and blood flow.

- For landmarks **above** the umbilicus the calculated temperature rise was 4.4°C for a whole body average SAR value of 2.0 W/kg and a continuous scan time of 15 minutes.
- For landmarks **below** the umbilicus the calculated temperature rise was 2.8°C for a whole body average SAR value of 1.0 W/kg and a continuous scan time of 15 minutes.

1.5 Tesla Temperature Information
In non-clinical testing, the Epic Stent at single lengths of 120 mm and overlapped lengths of 155 mm produced a maximum temperature rise of 3.2°C at a maximum whole body averaged of 2 W/kg, that was determined by validated calculation for 15 minutes of MR scanning in a 1.5 Tesla Philips Intera®, software version Release 10.6.2.4, 2006-03-10 MR scanner. In this model, the reported temperatures are conservative as they do not take into account the cooling effects of perfusion and blood flow.

- For landmarks **above** the umbilicus the calculated temperature rise was 3.2°C for a whole body average SAR value of 2.0 W/kg and a continuous scan time of 15 minutes.
- For landmarks **below** the umbilicus the calculated temperature rise was 2.7°C for a whole body average SAR value of 1.0 W/kg and a continuous scan time of 15 minutes.

Image Artifact
The image artifact extends approximately 1.25 mm from the perimeter of the device diameter and 2 mm beyond each end of the length of the stent when scanned in non-clinical testing using the sequence, Spin Echo. With a Gradient Echo sequence the image artifact extends 1.25 mm beyond the perimeter of the device diameter and 3 mm beyond each end of the length of the stent with both sequences partially shielding the lumen in a 3.0 Tesla Siemens Medical Solutions, software version Numaris/4, Syngo MR 2004A 4VA25A MR system with a transmit/receive CP head coil. Image artifacts in a body birdcage coil are similar to the image artifacts in the transmit/receive CP head coil.

Recommendations
It is recommended that patients register the conditions under which the implant can be scanned safely with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.

ADVERSE EVENTS

Potential adverse events that may occur following intravascular stent implantation include, but are not limited to:

- Abscess
- Allergic reaction (to drug, contrast, device or other)
- Amputation
- Aneurysm
- Angina/coronary ischemia
- Arrhythmia
- Arteriovenous fistula
- Death
- Drug reactions
- Embolization (air, plaque, thrombus, device, or other)
- Entanglement of delivery system in deployed stent
- Fever
- GI bleeding
- Hemorrhage/hematoma
- Hypotension/hypertension
- Myocardial Infarction (MI)
- Need for urgent intervention or surgery
- Pseudoaneurysm
- Renal insufficiency or failure
- Restenosis of stented artery
- Sepsis/infection
- Stent fracture
- Stent migration
- Stent misplacement/jumping
- Stent thrombosis with possible neurological injury
- Stroke
- Thrombosis/thrombus
- Tissue ischemia/necrosis
- Vasospasm
- Vessel injury, examples include perforation, dissection, intimal tear, rupture
- Vessel occlusion

ORION Clinical Trial

A total of 125 subjects were treated at 28 centers in this prospective, single arm, non-randomized, multicenter trial. **Table 1** presents the principal effectiveness and safety results for the ORION trial through 9-months post-index procedure. **Figure 1** displays the Kaplan-Meier curve for Major Adverse Events (MAEs) through the 270 days. Four subjects (3.4%) had an MAE as adjudicated by an independent Clinical Events Committee (CEC). There were four subjects with Target Vessel Revascularization (TVR) through 9 months, no deaths through 30 days, no index hospitalization myocardial infarctions (MI), and no amputations through 9 months.

Table 1. Primary Effectiveness and Safety Results, All Subjects (N=125)

	(N=125 Subjects)	[95% CI]
9-Month MAE (per subject)	3.4% (4/117)	[0.9%, 8.5%]
Device- or index procedure-related Death within 30 days	0.0% (0/117)	[0.0%, 3.1%]
Myocardial Infarction (MI) during index hospitalization	0.0% (0/117)	[0.0%, 3.1%]
Target Vessel Revascularization (TVR) through 9 months	3.4% (4/117)	[0.9%, 8.5%]
Amputation of index limb through 9 months	0.0% (0/117)	[0.0%, 3.1%]

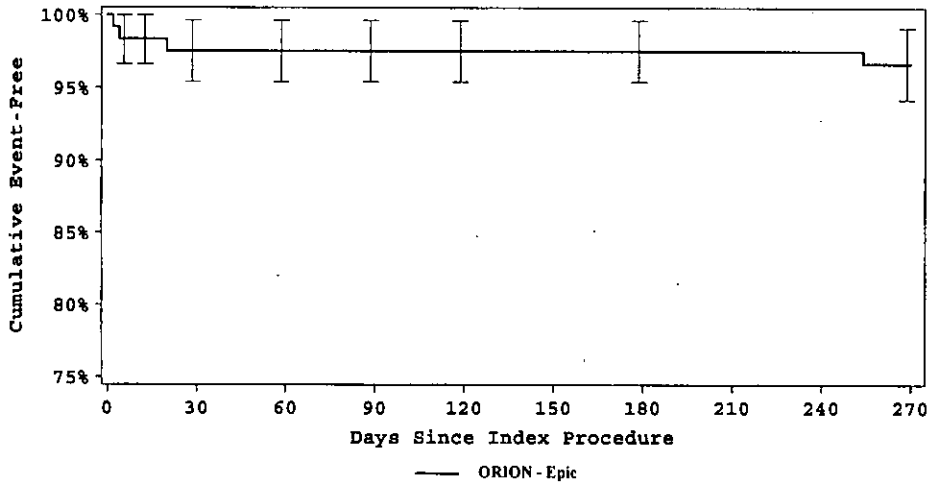

Figure 1. Freedom from 9 month MAE, Event-Free Survival ± 1.96 SE, All Subjects (N=125)

Objective: To determine whether the Epic™ Stent for primary stenting of iliac atherosclerotic lesions showed acceptable performance at 9 months.

Design: The ORION Trial was a prospective, single-arm, non-randomized clinical trial conducted at 28 centers in the US. A total of 125 subjects were enrolled.

Subjects considered for enrollment had documented chronic, symptomatic iliac artery atherosclerotic disease (Rutherford/Becker category 1, 2, 3 or 4) with lifestyle-limiting claudication or rest pain. Target lesions were de novo or restenotic from prior PTA and located in the common and/or external iliac artery. Lesion length was ≤13cm with reference vessel diameter (RVD) ≥5 mm to ≤11 mm and baseline lesion stenosis ≥50% (all visually assessed). A subject could receive a maximum of 2 study stents for up to 2 target lesions. Two target lesions in the same target vessel could be treated if there was a 20 mm non-treated segment between the 2 implanted study stents. Subjects with bilateral disease could have only 1 target lesion treated per side. Subjects with uncorrected bleeding disorders; intolerance to anticoagulation, antithrombolytic or antiplatelet medications; intraluminal thrombus of the proposed treated lesion(s) post thrombolytic therapy or known allergy to nitinol were excluded from the study.

Before the stenting procedure, subjects were administered anticoagulation and antiplatelet therapy consistent with current clinical practice. After the procedure antiplatelet therapy was to be prescribed throughout the subject's participation in the study.

Enrolled subjects were evaluated in the office at baseline, index procedure, pre-discharge, 1 month, and 9 months post-index procedure. Additional follow-up evaluations are ongoing and will occur in the office at 12 months and by phone contact at 2 and 3 years post-index procedure. ABI, Rutherford Classification and Duplex ultrasound follow-up are performed at 1, 9 and 12 months. The Walking Impairment Questionnaire is administered at baseline, 9 and 12 months.

Endpoints: The Primary Endpoint was the 9-month device- and/or procedure-related major adverse event (MAE) rate (subject-based), adjudicated by an independent CEC. MAE was defined as death within 30 days, myocardial infarction (MI) that occurs during index hospitalization, target vessel revascularization (TVR) through nine months, and/or amputation of index limb through nine months.

Secondary Endpoints through 30 days included:

- Technical success (residual stenosis ≤30% based on visual assessment immediately post-procedure)
- Procedural success (technical success and no in-hospital major adverse events)
- Early clinical success at hospital discharge and 30 days post-procedure: improvement in Rutherford classification by ≥1 class as compared to baseline
- Early hemodynamic success at hospital discharge and 30 days post-procedure: improvement in Ankle-Brachial Index (ABI) by ≥0.1 as compared to baseline
- Frequency distribution of Rutherford classification preprocedure and at 30 days postprocedure
- Target vessel revascularization (TVR)
- Target lesion revascularization (TLR)
- Amputation of index limb
- Myocardial infarction (MI) that occurs during index hospitalization
- Death
- Stent thrombosis

Secondary Endpoints through 9 months included:

- Late clinical success at 9 months post-procedure: improvement in Rutherford classification by ≥1 class as compared to baseline
- Frequency distribution of Rutherford classification at 9 months
- Primary, primary-assisted, and secondary patencies at 9 months as assessed by duplex ultrasound
- Restenosis at 9 months as assessed by duplex ultrasound
- Late hemodynamic success at 9 months postprocedure: improvement in ABI by ≥0.1 as compared to baseline
- Change in Walking Impairment Questionnaire scores at 9 months postprocedure
- Target vessel revascularization (TVR)
- Target lesion revascularization (TLR)
- Amputation of index limb
- Death
- Stent thrombosis
- Incidence of unanticipated adverse device effects
- Incidence of all serious adverse events (SAE) reported within the trial
- Incidence of all non-serious adverse events reported within the trial

For the primary endpoint of 9-month MAE, an exact, one-sided 95% upper confidence bound was calculated and compared to the prespecified performance goal. The performance goal of 17% included an expected 9-month MAE rate of 8.0% for Epic and for iliac artery stenting with self-expanding stents based on published literature plus a margin of 9.0%. The upper confidence bound was less than the performance goal; therefore, the primary endpoint was met and the Epic™Stent System demonstrated acceptable performance.

Demographics: Baseline characteristics of the ORION clinical trial showed 64.8% were males. The average age was 61.1 (range 39 to 83 years), 96.0% were current or previous smokers, 36.8% had current diabetes mellitus, 78.4% had a history of hyperlipidemia and 76.0% had history of hypertension. Baseline lesion characteristics included mean reference vessel diameter (RVD) of 7.69 mm, mean luminal diameter (MLD) of 2.20 mm, mean percent diameter stenosis (%DS) of 71.51% and mean lesion length of 31.04 mm.

Table 2 presents baseline demographic and clinical characteristics. **Table 3** summarizes baseline lesion characteristics.

Table 2. Baseline Demographics and Clinical Characteristics, All Subjects (N=125)

Variable	(N=125 Subjects)
Demographics	
Age, Mean±SD (N), (min,max)	61.09±9.25 (125) (39.00, 83.00)
Male Gender	64.8% (81/125)
Race/Ethnicity	
Hispanic or Latino	2.4% (3/125)
Caucasian	89.6% (112/125)
Asian	0.0% (0/125)
Black, or African heritage	6.4% (8/125)
Native Hawaiian or other Pacific Islander	0.0% (0/125)
American Indian or Alaska Native	0.8% (1/125)
Other	0.8% (1/125)
General Medical History	
History of Smoking	96.0% (120/125)
Current Diabetes Mellitus	36.8% (46/125)
History of Hyperlipidemia	78.4% (98/125)
History of Hypertension	76.0% (95/125)
History of COPD	24.8% (31/125)
Cardiac History	
History of CAD	58.4% (73/125)
History of MI	28.0% (35/125)
History of PCI	36.8% (46/125)
History of CABG	17.6% (22/125)
Neurologic/Renal History	
History of Transient Ischemic Attacks	4.0% (5/125)
History of Cerebrovascular Accident	5.6% (7/125)
History of Renal Insufficiency	7.2% (9/125)
Peripheral Vascular History	
History of Peripheral Vascular Surgery	8.0% (10/125)
History of Other Peripheral Endovascular Interventions	20.0% (25/125)
History of Claudication	92.8% (116/125)

Table 3. Baseline Lesion Characteristics – Core Lab, All Lesions (N=166)

Lesion Characteristic	(N=166 Lesions)
Iliac Artery Segment	
Left Common Iliac Artery	36.3% (58/160)
Left External Iliac Artery	10.0% (16/160)
Right Common Iliac Artery	36.3% (58/160)
Right External Iliac Artery	17.5% (28/160)
Reference Vessel Diameter (RVD, mm)	7.69±1.79 (160) (4.61, 12.79)
Stent Size to RVD Ratio	1.19±0.25 (160) (0.68, 1.87)
Minimum Lumen Diameter (MLD, mm)	2.20±1.34 (160) (0.00, 5.44)
Percent Diameter Stenosis (% DS)	71.51±16.27 (160) (39.78, 100.00)
Lesion Length (mm)	31.04±22.13 (160) (4.08, 130.10)

Methods: Clinical follow-up was conducted in the office at baseline, index procedure, pre-discharge, 30 days, and 9 months.

Results: **Table 4** presents the 9-month MAE rate (primary endpoint) of 3.4% (4/117) with a one-sided upper confidence bound of 7.7%, significantly less than the performance goal of 17.0% (P<0.0001). The ORION study met its primary endpoint, supporting safety and efficacy of the Epic™ Stent System. Four subjects (3.4%) had an MAE as adjudicated by an independent CEC. There were 4 subjects with TVR through 9 months, no deaths through 30 days, no index hospitalization MI, and no amputations through 9 months.

Table 4. Primary Endpoint Performance Goal Assessment, All Subjects (N=125)

Measure	(N=125 Subjects)	One-sided 95% Upper Confidence Bound	Performance Goal	p-Value*
9-Month MAE	3.4% (4/117)	7.7%	17.0	<0.0001

*P-value is from the one-sided exact-test

All subjects enrolled in the ORION trial received an Epic Stent. Technical success was achieved in 100% of the lesions treated and procedural success was achieved in 99.2% of the subjects in the study. One subject had an MAE prior to hospital discharge.

Late clinical success was achieved in 89.9% of the subjects and late hemodynamic success was achieved in 66.7% of the treated limbs. Lesion based rates for primary patency and restenosis were 95.9% and 4.1% respectively.

Principal effectiveness and safety results are summarized in **Tables 5** and **6**.

Table 5. Principal Effectiveness and Safety Results, (N=125 Subjects; N=162 Limbs; N=166 Vessels; N=166 Lesions)

Parameter	Epic[a]
9-Month Clinical Outcomes	
Subject based	
Major adverse events (MAE) through 9 months[b]	3.4% (4/117)
Device- or index procedure-related death within 30 days	0.0% (0/117)
Myocardial infarction (MI) during index hospitalization	0.0% (0/117)
Target vessel revascularization (TVR) through 9 months	3.4% (4/117)
Amputation of index limb through 9 months	0.0% (0/117)
Late clinical success[c]	89.9% (98/109)
Death	0.9% (1/117)
Stent thrombosis	2.6% (3/117)
Stent thrombosis within 30 days	2.5% (3/121)
Acute (≤24 hours post index procedure)	0.0% (0/121)
Subacute (>24 hours to ≤30 days post index procedure)	2.5% (3/121)
Lesion based	
Primary patency	95.9% (117/122)
Primary-assisted patency	98.4% (120/122)
Secondary patency	100% (120/120)
Restenosis	2.5% (3/122)
Target lesion revascularization (TLR)	3.2% (5/156)
Limb based	
Early hemodynamic success[d]	
Hospital discharge	61.2% (93/152)
30 days	66.2% (100/151)
Late hemodynamic success[e]	66.7% (94/141)
Vessel based	
TVR	3.2% (5/156)
Peri-procedural Endpoints	

Parameter	Epic[a]
Technical success (per lesion)[f]	100% (166/166)
Procedure success (per subject)[g]	99.2% (124/125)

Numbers are % (counts/sample size) or mean±SD (n); outcomes are based on protocol definitions.

a: Two subjects did not complete a 9-month follow-up visit but did return for a 1-year visit. Data for these 2 subjects are included in primary endpoint calculations for MAE n=117.

b: Includes death within 30 days, MI that occurs during index hospitalization, TVR through 9 months, and/or amputation of index limb through 9 months

c: Improvement in Rutherford classification at 9 months by ≥1 class as compared to baseline

d: Improvement in ankle-brachial index at hospital discharge and 30 days by ≥0.1 as compared to baseline

e: Improvement in ankle-brachial index at 9 months by ≥0.1 as compared to baseline

f: Residual stenosis ≤30% based on visual assessment immediately post-procedure

g: Residual stenosis ≤30% based on visual assessment immediately post-procedure and no in-hospital MAE

Table 6. Summary of Patency and Restenosis Results at 9 Months due to Alternate Analysis, (All Lesions (N=166) in all Subjects (N=125)

	Epic*
Lesion Based	
Primary-assisted patency	96.7% (118/122)
Secondary patency	98.3% (118/120)
Restenosis	4.1% (5/122)

*Two cases of restenosis and TLR occurred in one subject (Left Common and Right Common Iliac Arteries) at the most proximal part of the stents (located at the ostium of both iliac arteries). In this case, the conventional method of deriving Systolic Velocity Ratio is invalid and the Proximal Peak Systolic Velocity was analyzed to assess restenosis at 9 months. These are the results after the alternate analysis has been applied.

The rates of center-reported serious adverse events (SAEs) are summarized by MedDRA System / Organ Class and MedDRA Preferred Term in **Table 7**. The rates include all reported serious events, regardless of study device or procedure relatedness.

Table 7. Rates of Center-Reported Serious Adverse Events to 300 Days Intent-to-Treat, All Subjects (N=125)

Serious Adverse Event		(N= 125 Subjects)	
MedDRA System/Organ Class	MedDRA Preferred Term	Events	Rate of Subjects with Event
Total	Total	88	32.0% (40/125)
Not Coded	Not Coded	1	0.8% (1/125)
Blood And Lymphatic System Disorders	Total	4	1.6% (2/125)
	Anaemia	2	0.8% (1/125)
	Febrile Neutropenia	1	0.8% (1/125)
	Haemorrhagic Anaemia	1	0.8% (1/125)
Cardiac Disorders	Total	23	12.8% (16/125)
	Acute Coronary Syndrome	1	0.8% (1/125)
	Angina Pectoris	3	2.4% (3/125)
	Angina Unstable	1	0.8% (1/125)
	Atrial Fibrillation	7	3.2% (4/125)
	Cardiac Arrest	1	0.8% (1/125)
	Coronary Artery Disease	4	2.4% (3/125)
	Coronary Artery Stenosis	1	0.8% (1/125)
	Ischaemic Cardiomyopathy	2	1.6% (2/125)
	Mitral Valve Stenosis	1	0.8% (1/125)
	Myocardial Infarction	2	1.6% (2/125)
Eye Disorders	Total	1	0.8% (1/125)
	Blindness	1	0.8% (1/125)
Gastrointestinal Disorders	Total	6	2.4% (3/125)
	Abdominal Pain	2	0.8% (1/125)
	Constipation	1	0.8% (1/125)

Serious Adverse Event		(N= 125 Subjects)	
MedDRA System/Organ Class	MedDRA Preferred Term	Events	Rate of Subjects with Event
	Gastrointestinal Haemorrhage	1	0.8% (1/125)
	Ileus	1	0.8% (1/125)
	Upper Gastrointestinal Haemorrhage	1	0.8% (1/125)
General Disorders And Administration Site Conditions	Total	5	4.0% (5/125)
	Catheter Site Haematoma	1	0.8% (1/125)
	Catheter Site Haemorrhage	1	0.8% (1/125)
	Chest Discomfort	1	0.8% (1/125)
	Non-cardiac Chest Pain	1	0.8% (1/125)
	Oedema Peripheral	1	0.8% (1/125)
Hepatobiliary Disorders	Total	3	1.6% (2/125)
	Bile Duct Stenosis	1	0.8% (1/125)
	Cholecystitis Acute	1	0.8% (1/125)
	Cholecystitis Chronic	1	0.8% (1/125)
Infections And Infestations	Total	8	4.0% (5/125)
	Abdominal Abscess	1	0.8% (1/125)
	Clostridial Infection	1	0.8% (1/125)
	Diverticulitis	2	0.8% (1/125)
	Pneumonia	3	2.4% (3/125)
	Wound Infection	1	0.8% (1/125)
Injury, Poisoning And Procedural Complications	Total	6	4.0% (5/125)
	Drug Toxicity	1	0.8% (1/125)
	Stent-graft Malfunction	2	1.6% (2/125)
	Vascular Pseudoaneurysm	2	1.6% (2/125)
	Wound Dehiscence	1	0.8% (1/125)
Investigations	Total	1	0.8% (1/125)
	Blood Creatinine Increased	1	0.8% (1/125)
Musculoskeletal And Connective Tissue Disorders	Total	2	1.6% (2/125)
	Lumbar Spinal Stenosis	1	0.8% (1/125)
	Pain In Extremity	1	0.8% (1/125)
Neoplasms Benign, Malignant And Unspecified (incl Cysts And Polyps)	Total	3	2.4% (3/125)
	Breast Cancer	1	0.8% (1/125)
	Lung Neoplasm Malignant	1	0.8% (1/125)
	Recurrent Cancer	1	0.8% (1/125)
Nervous System Disorders	Total	4	3.2% (4/125)
	Carotid Artery Stenosis	1	0.8% (1/125)
	Diplegia	1	0.8% (1/125)
	Headache	1	0.8% (1/125)
	Hypoaesthesia	1	0.8% (1/125)
Psychiatric Disorders	Total	1	0.8% (1/125)
	Mental Status Changes	1	0.8% (1/125)
Respiratory, Thoracic And Mediastinal Disorders	Total	7	3.2% (4/125)
	Acute Pulmonary Oedema	1	0.8% (1/125)
	Acute Respiratory Failure	1	0.8% (1/125)
	Chronic Obstructive Pulmonary Disease	4	1.6% (2/125)
	Pneumonia Aspiration	1	0.8% (1/125)
Vascular Disorders	Total	13	8.8% (11/125)
	Angiodysplasia	1	0.8% (1/125)
	Arterial Stenosis	1	0.8% (1/125)
	Iliac Artery Thrombosis	1	0.8% (1/125)
	Intermittent Claudication	2	1.6% (2/125)
	Peripheral Artery Dissection	3	2.4% (3/125)
	Peripheral Ischaemia	1	0.8% (1/125)
	Peripheral Vascular Disorder	1	0.8% (1/125)

Serious Adverse Event		(N= 125 Subjects)	
MedDRA System/Organ Class	MedDRA Preferred Term	Events	Rate of Subjects with Event
	Thrombosis	1	0.8% (1/125)
	Vascular Occlusion	1	0.8% (1/125)
	Vessel Perforation	1	0.8% (1/125)

Conclusions: The ORION trial demonstrated the Epic™ Stent System to be safe and effective in the treatment of atherosclerotic iliac artery disease.

HOW SUPPLIED

Handling and Storage
Do not use if package is opened or damaged.
Do not use if labeling is incomplete or illegible.
Upper Temperature Limit: 55°C

Store in a cool, dark, dry place.

RECOMMENDED MATERIALS
- 0.035 in (0.89 mm) guidewire of appropriate length
- Introducer sheath of appropriate size and length and equipped with a hemostatic valve
- Syringe (10 ml (cc) for prepping the stent delivery system)

OPERATIONAL INSTRUCTIONS

Patient Preparation

The percutaneous placement of an iliac self-expanding nitinol stent in a stenotic or obstructed artery should be done in an angiography procedure room equipped with the appropriate imaging equipment. Patient preparation and sterile precautions should be the same as for any angioplasty procedure. Appropriate antiplatelet and anticoagulation therapy must be administered pre- and post-procedure in accordance with standard practices. Angiography should be performed to map out the extent of the lesion(s) and the collateral flow. Access vessels must be sufficiently patent, to proceed with further intervention. If thrombus is present or suspected, thrombolysis should precede stent deployment using standard acceptable practice.

Inject Contrast Media

Perform angiogram using standard technique.

Evaluate and Mark the Stenosis

Observe fluoroscopically the most distal view of the stenotic or obstructed artery.

Select Proper Stent System

1. Measure the diameter of the reference vessel (proximal and distal to the lesion or obstruction) and use the largest reference diameter as your basis for choosing the appropriate stent size. Select a stent per **Table 8** below to achieve a secure placement:
   Warning: Improper stent size selection may lead to stent migration or stent jumping.

Table 8

Reference Vessel Diameter (mm)	Labeled Stent Diameter (mm)
5	6
5-6	7
6-7	8
7-8	9
8-9	10
9-11	12

2. Measure the entire length of the actual lesion and select the proper length of the stent(s) to be deployed. In-vitro testing has predicted the Epic Stent foreshortens 4.2% (for 6-7 mm diameters), 5.2% (for 8-10 mm diameters) and 8.1% (for 12 mm diameter) when used in the recommended vessel diameters. To help ensure adequate apposition, it is recommended that the length of the stent be chosen so that the ends of the stent extend at least 5 mm beyond both ends of the lesion into healthy tissue. Should more than one stent be required to cover the lesion, allow for at least 5 mm of stent overlap. It is generally recommended that the distal stent be placed first.
3. Estimate the distance between the lesion and the entry site to select the proper stent delivery system length.

Preparation of Stent Delivery System

1. Open the outer box to reveal the pouch containing the stent delivery system.
2. Check the temperature exposure indicator on the pouch label to confirm that the product has not been compromised. See Warnings section.
3. After careful inspection of the pouch looking for damage to the sterile barrier, carefully peel open the pouch, and extract the stent delivery system tray.
4. Open the door on the tray that contains the handle.
5. Carefully withdraw the stent delivery system from the tray by grasping the handle of the delivery system.
6. Examine the device for any damage. If it is suspected that the sterility or performance of the device has been compromised, the device should not be used.
7. If the safety lock (3) (Reference **Figure 2**) is not attached to the device, verify that the stent is fully constrained in the delivery system and place safety lock in position as shown in **Figure 2**.
8. Attach a 10 ml (cc) syringe filled with saline to the luer on the handle. Apply positive pressure. Continue to flush until saline appears at the distal end of both the guidewire lumen and the sheath – tip junction.
9. Remove the flushing luer (7) (Reference **Figure 2**).

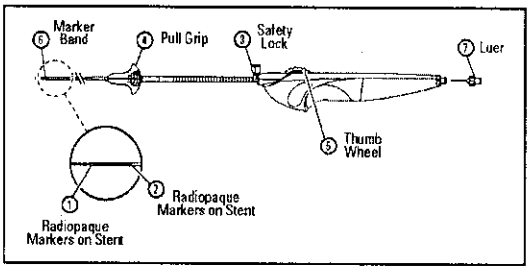

Figure 2

Delivery Procedures

1. Gain arterial access utilizing a 6F (2.1 mm) or larger sheath with a hemostatic valve.
   Precaution: Always use an introducer or guide sheath for the implant procedure, to protect the access site.
2. Pass a 0.035 in (0.89 mm) guidewire of appropriate length across the target lesion or obstruction.
3. Pre-dilate the lesion as necessary with a balloon dilatation catheter using conventional technique. After the lesion has been properly dilated, remove the dilatation catheter, leaving the guidewire with the tip distal to the lesion for stent system advancement.
   Precaution: Physicians should use judgment based on experience in dilating arterial lesions and/or obstructions. Never force a balloon catheter to inflate to the point of risking dissection of the arterial wall.
4. Place the Epic™ Stent System over the guidewire. Advance the delivery system as a unit through the hemostatic valve of the introducer sheath.

Stent Deployment Procedure (Reference Figure 2)

1. Advance the delivery system until the stent radiopaque markers (1) and (2) are centered over the target lesion.
   Warnings:
   - If unable to initiate release of the stent or if strong resistance is met with the introduction of the delivery system, remove the entire system from the patient and introduce a new system.
   - Remove all slack from the catheter prior to stent deployment, as excessive slack may result in stent jumping or the stent length being reduced.

   Precaution: Do not use a power injector through the delivery system for angiography.
2. Remove the safety lock positioned on the rack (3) by pulling vertically. Confirm that the radiopaque markers are still properly positioned across the target lesion. Keep the entire length of the delivery system as straight as possible and maintain slight backward tension on the delivery system during deployment.
   Note: If repositioning of the delivery system is required prior to stent deployment, reinsert the safety lock to prevent inadvertent deployment.
3. Prior to initiating stent deployment, make sure to keep the stent delivery catheter stationary. Do not hold the outer sheath of the delivery catheter during deployment as it must be free to move.
4. Start deploying the stent by slowly rotating the thumb wheel (5). Allow the stent to contact and anchor to the vessel wall and then proceed with one of the following methods:

   - Roll the thumb wheel (5) of the deployment handle in a proximal direction. Continue to roll thumb wheel until the radiopaque marker of the exterior shaft (6) passes the proximal radiopaque markers of the stent resulting in full deployment. Do not continue to roll the thumb wheel after the stent is fully deployed.
     Note: Do not restrict movement of the thumb wheel (5) otherwise deployment difficulties could be encountered.
   - Grasp the manual pull grip (4) and pull toward the deployment handle. Continue to pull back until the radiopaque marker of the exterior shaft (6) passes the proximal radiopaque markers of the stent resulting in full deployment. Do not continue to pull back the manual grip after the stent is fully deployed.
   - Any combination of the methods above can be used to achieve full deployment.

5. When released from the delivery system, the stent will immediately expand into position. View the delivery system under fluoroscopy, ensuring that the exterior shaft marker band (6) has crossed the proximal stent markers. The delivery system can now be withdrawn. Use caution when withdrawing the stent delivery system and always manipulate under fluoroscopy. If unusual resistance is felt, re-advance and rotate the delivery system in an attempt to center the delivery system within the vessel, and then carefully attempt repeat withdrawal.

6. If incomplete expansion exists within the stent at any point along the lesion, balloon dilatation can be performed utilizing standard PTA technique.
   Precaution: Never dilate the stent using a balloon that is larger in diameter than the labeled diameter of the stent.
7. Withdraw guidewire and sheath from patient and establish hemostasis per conventional technique.

Post Procedure
Assess patient for hematoma and/or other signs of bleeding at the puncture site.

REFERENCES
The physician should consult recent literature on current medical practice on stent implantation.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

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One Boston Scientific Place
Natick, MA 01760-1537
USA
USA Customer Service 888-272-1001

Recyclable Package

YYYY-MM

Magnetic Resonance Conditional

Non-clinical testing has demonstrated the Epic™ Vascular Self-Expanding Stent System is MR Conditional. It can be scanned safely up to a total length of 155 mm and overlapping stents up to 155 mm under the following conditions:

- Static magnetic field of 3 Tesla and 1.5 Tesla
- Spatial gradient field of 2560 Gauss/cm
- Normal operating mode only with a maximum whole body (WB) averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of active scanning for patient landmarks above the umbilicus (patient navel).
- Maximum WB-SAR of 1 W/kg for 15 minutes of scanning for patient landmarks below the umbilicus.
- Use whole body transmit/receive coil only. Do not use local transmit coils. Local receive coils can be used.

MRI at 3 T or 1.5 T may be performed immediately following the implantation of the Epic Self-Expanding Nitinol Stent. This stent has not been evaluated to determine if it is MR Conditional beyond these conditions.

It is recommended that patients register the conditions under which the implant can be scanned safely with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

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Cardiology, Rhythm and Vascular
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Natick, MA 01760-1537 USA
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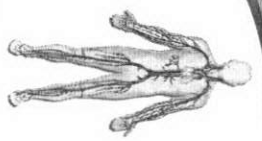

Epic™ Vascular
Self-Expanding Stent System

For more information about indications, contraindications, warnings and instructions for the Epic™ Vascular Self-Expanding Stent System, visit **www.bostonscientific.com.**

You can also call Boston Scientific customer service at **1.888.272.1001** to request copies of the Directions for Use (DFU).

CAUTION: Federal (USA) law restricts these products to sale by or on the order of a doctor.

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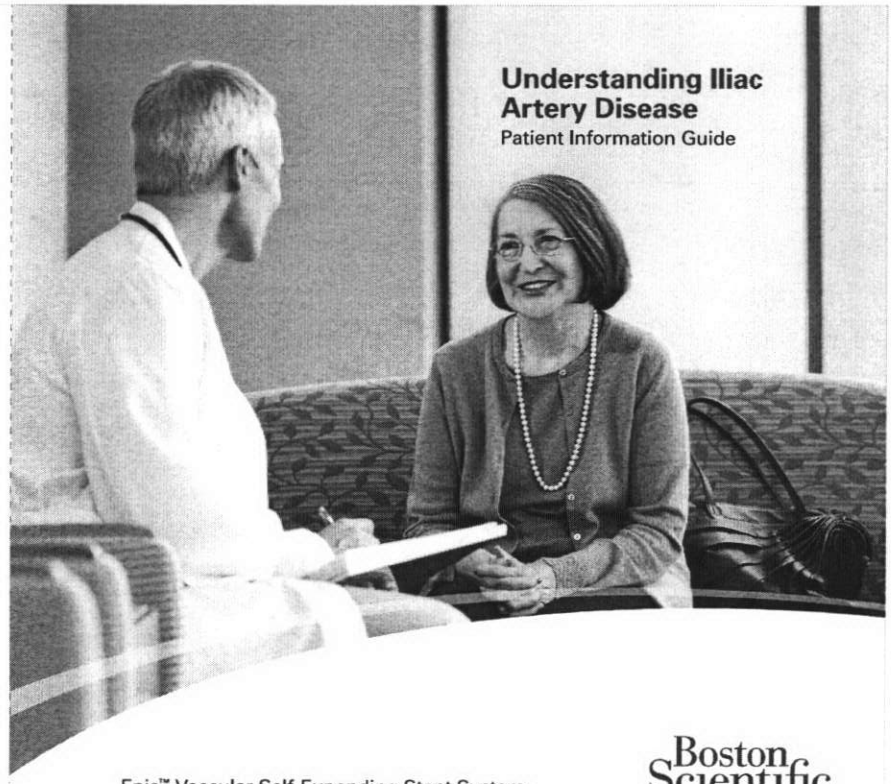

Understanding Iliac Artery Disease

Patient Information Guide

Epic™ Vascular Self-Expanding Stent System

Boston Scientific

Patient Name	Emergency Contact Number
Implanting Physician's Name	Stent Material
Physician's Phone Number	Date of Implant

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Table of Contents

Glossary

Angioplasty
A minimally invasive treatment of the arteries that opens blocked arteries.

Anticoagulant and Antiplatelet
Medicines that slow down the clotting of blood.

Artery
A blood vessel that carries oxygen-rich blood away from the heart to the rest of the body.

Atherosclerosis
A disease in which the flow of blood is slowed down by plaque in the arteries.

Balloon Angioplasty
Inflating a balloon catheter in the blood vessel to open a blocked artery.

Balloon Catheter
A thin tube with a balloon attached to the tip that can be inflated to open blocked arteries.

Blood Vessel
Any of the veins and arteries that carry blood to and from the heart.

Catheter
A long, flexible tube that can be passed through the blood vessels.

Contrast
X-ray dye used in diagnostic tests.

Iliac Arteries
The blood vessels that supply blood to the legs.

Iliac Artery Bypass
A surgical procedure used to create an alternate route for blood to flow to the legs around narrowed or blocked iliac arteries.

Iliac Artery Endarterectomy
A surgical procedure that removes plaque from the walls of the Iliac arteries.

Glossary continued

Minimally Invasive Procedure
A procedure that uses small instruments or devices to reduce the size of the insertion site and cause a smaller amount of trauma

MRI (Magnetic Resonance Imaging)
A method of using a magnetic field and radio waves to produce detailed images of the inside of the human body.

Occlusion
Blockage of blood flow in the artery.

Peripheral
Related to areas of the body outside the heart and brain.

Plaque
A buildup of cholesterol, fat calcium and collagen in a vessel.

Restenosis
Re-narrowing of the artery after treatment.

Sedative
A type of medication that makes you relaxed and sleepy. Also called sedation.

Stenosis
A narrowing of the artery.

Stent
A metal tube that supports the blood vessel wall and maintains blood flow through the opened vessel.

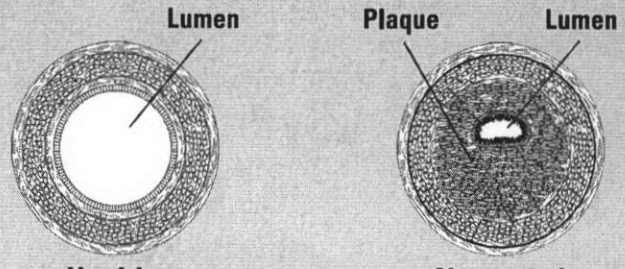
Treating iliac artery disease

Your doctor wants you to have a stent placed in your iliac artery. This is to help treat your iliac artery disease. This guide explains the procedure and what you can expect from start to finish. A glossary at the beginning of this guide defines common medical terms about this procedure.

You will also learn steps you can take to live a healthier life with iliac artery disease.

What is iliac artery disease?

Iliac artery disease is caused by the narrowing of the arteries leading to the legs. This narrowing can also be called a stenosis. It is usually caused by a buildup of fat or calcium deposits called plaque. Over time, this plaque can build to a total blockage of the artery. This is also called atherosclerosis.



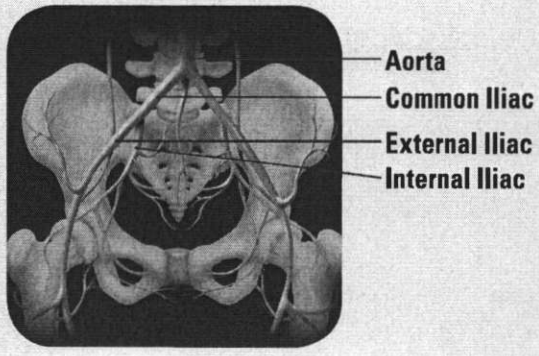
Healthy Iliac Artery

Narrowed Iliac Artery

When a leg doesn't receive enough blood flow because of a blockage in an artery, it can cause pain in the lower leg when walking. In severe cases, low blood flow can cause tissue loss.

Iliac Arteries

You have two iliac arteries, one located at the top of each leg. The iliac arteries start at the base of the aorta, just behind the navel (belly button). The iliac arteries branch into smaller arteries that supply blood to the legs and feet.



Iliac artery disease treatment options

There are four different treatment options for iliac artery disease. All four treatment options focus on increasing blood flow to the legs. The type of treatment your doctor recommends depends on your symptoms.

1. **Medical therapy**
   For patients with mild to medium symptoms, doctors often choose medical therapy. This can include drugs, exercise, and regular checkups. Doctors also say to stop smoking. The doctor may prescribe drugs to decrease clotting, lower blood pressure, and reduce cholesterol. Regular checkups can help determine if more treatment is needed.

2. **Angioplasty**
   A procedure, angioplasty, can also treat vessel narrowing. A thin tube known as a catheter is inserted into the artery. A small balloon located on the tip of a catheter is moved to the site of the narrowing and inflated to expand the artery and reduce the blockage. The balloon is deflated and removed after the angioplasty is done. Angioplasty is less invasive than surgery, and the patient remains awake while the doctor performs the procedure.

3. **Iliac artery stenting**
   During this procedure, a small mesh tube, called a stent, is placed in the artery which keeps the artery open and helps prevent re-narrowing.

4. **Surgery**
   For patients with severe narrowing with blocked blood flow to the legs, surgery may be needed. There are two types of surgery to treat iliac artery disease. During an iliac artery endarterectomy, the doctor makes an incision in the pelvis. This exposes the iliac artery and the plaque inside the artery is removed. Patients who have this type of surgery are usually in the hospital for about a week. In an iliac artery bypass, a healthy vein is removed from another part of your body. This vein is used to make a new path around the narrowed or blocked iliac artery, or alternatively, a synthetic (plastic) artery may be used. Patients are also in the hospital for about a week after this surgery.

Risks

Your doctor may not consider you to be a good candidate for stenting if you have any of the following conditions:

- You are unable to take medicines that make your blood take longer to clot (anticoagulants).
- You are unable to take medicines, such as Aspirin or Plavix, that make your blood cells slippery and make it more difficult for your blood to clot (antiplatelets).
- You are allergic to nickel or titanium. These are the metals used to make up the Epic™ Vascular Self-Expanding Stent System. Discuss the potential for allergy with your doctor if you have ever experienced a skin rash to jewelry, watches, or belt buckles.
- You have poor kidney function.

Note: It is very common for your doctor to prescribe specific medications before, during and after your stent placement. Common drugs that may be prescribed by your doctor include anticoagulants and antiplatelets. These medications are intended to help decrease the risk of forming a blood clot in your artery. Please check with your doctor to find the right medication for you.

Risks continued

The placement of stents in blood vessels is done to treat blockages and to try to prevent re-narrowing.

As with any stent procedure, there is chance that complications may occur, including, but not limited to, the following:

- Air bubble(s) in your artery
- Allergic reactions
- Amputation
- Bleeding
- Blood clot(s)
- Bruising at your groin area
- Death
- Fever
- GI bleeding
- Heart attack
- Infection
- Injury or damage to your artery or wall of the artery. This could require emergency surgery.
- Kidney damage or failure
- Nausea or vomiting
- Pain or discomfort
- Restenosis or re-narrowing of the artery around or within the stent
- Stent fracture
- Stent migration
- Stent misplacement/jumping
- Stroke
- Temporary change in blood pressure during the procedure
- Temporary changes in the rhythm of your heart during the procedure, although this is very rare
- Vasospasm

Your doctor and the medical staff will monitor you during and after the procedure for complications. If a complication does occur, your doctor will decide if you require treatment. In the event of complications, surgical removal of the stent may be required.

Benefits

The benefits of undergoing iliac stent placement may result in improved blood flow to your legs through the artery being treated. This may translate into less leg pain, less resting pain, improved quality of life, and improved ability to walk and move around.

Clinical data summary

The safety and effectiveness of the Epic™ Vascular Self-Expanding Stent System was established in the ORION clinical study, which included 125 patients with 9 month data (clinical follow up is ongoing through 3 years). The results showed that patients who received the Epic Vascular Self-Expanding Stent System had rates of major adverse events similar to what has been reported for comparable patients in the published literature. The occurrence of major adverse events at 9 months was 3.4% for the Epic Self-Expanding Stent System. Major adverse events included death within 30 days, procedural heart attack, bypass surgery and repeat angioplasty in the lesion where the stent was placed, and amputation.

All major adverse events observed were related to repeat angioplasty in the lesion where the stent was placed. Within the ORION study no deaths within 30 days, no heart attacks during the procedure and no by-pass surgery or amputations have occurred.

Before your procedure

Below is a typical checklist. Your doctor may ask you to go through this before your procedure.

- ☐ Tell your doctor about any medications you are taking.
- ☐ Take all your medications with you.
- ☐ Let your doctor know about any allergies you have. It is important he or she knows about allergies to contrast dye, iodine, cobalt, chromium, nickel, titanium, stainless steel or plastics.
- ☐ Tell your doctor if you cannot take aspirin or blood thinning medicines. These medications are usually prescribed before and after your procedure.
- ☐ Do not eat or drink anything after midnight on the night before your procedure.
- ☐ Follow the instructions you receive from your doctor and nurses.
- ☐ Make sure you understand the possible risks and benefits of your iliac stent procedure.
- ☐ You could be given a sedative to relax you before starting your stent procedure. The sedative can make you sleepy.

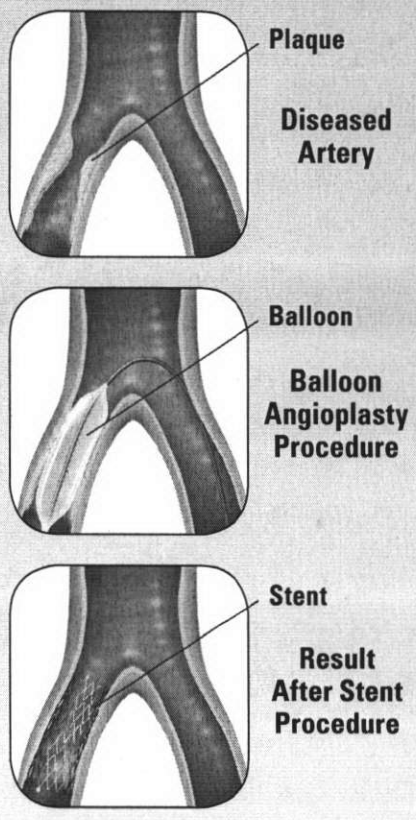
During a typical iliac artery stenting procedure

1. A small puncture is made in your groin to gain access to the iliac artery. A wire is then moved up into the iliac artery. A catheter is then put in your body. The doctor moves it to the narrowed section of your iliac artery. All wire and catheter movement is done using x-rays for a guide.

2. The diseased artery first needs to be enlarged to make room for the stent. To do this, the doctor places a small, deflated balloon over the wire and through the catheter to the blocked area of the iliac artery. When the balloon is in the correct position, it is inflated. This pushes the plaque buildup aside and reopens the artery to restore blood flow.

3. The balloon is deflated and removed, and a small metal mesh tube called a stent is placed into the same blocked area of the artery.

4. After the stent is implanted, the catheter and wire are removed and the puncture site in your groin is closed. The stent remains in place and is designed to help keep the artery open and prevent future narrowing of the iliac artery.



Images courtesy of Boston Scientific.
Images are for illustration purposes only, and are not necessarily to scale.

After a typical iliac stenting procedure

- You may feel sleepy from the sedative given to you. This will wear off over the next few hours.
- You will be taken to a unit where nurses and doctors can monitor you.
- Your heart rate, blood pressure, brain function and the entry site in your groin will be checked frequently.
- You will be asked to drink a lot of liquids to flush the contrast dye out of your system. You will have to stay in bed for several hours. You will be asked to keep your leg straight so the entry site in your groin can heal well.
- You may need a short hospital stay.
- You should alert your doctor or nurse if you experience any of these symptoms
  - Leg or foot pain
  - Unusual coldness and/or pallor in the leg or foot
  - Numbness in the leg or foot
  - Reappearance of the symptoms you had before treatment
  - Pain, bleeding or infection at the entry site in your groin
- You should avoid straining yourself or lifting items heavier than 5 pounds until your doctor lets you know that it is okay to do so.
- You should keep all follow-up appointments requested by your doctor.

Your stent implant card

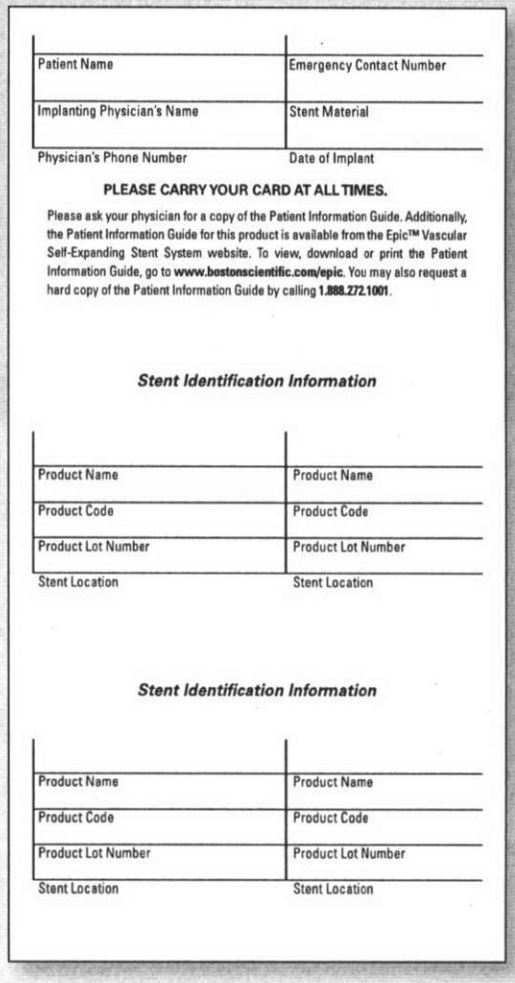
Your stent implant card shown at right tells doctors, dentists and nurses that you have a stent implanted in your iliac artery. This card also has:

- The doctor who put in your stent
- The doctor's phone number
- The date the stent was put in
- Where the stent was placed in your Iliac artery
- The size of the stent
- The manufacturer's lot number for the stent

The card gives your doctors, dentists and nurses information that is needed if you have any special diagnostic tests such as:

- MRI

There are also phone numbers on the card that your doctors can call if they have any questions. Your discharge nurse will fill in the card. If he or she does not, please call the doctor who placed the stent for this information.



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Living with iliac artery disease

Treatment for iliac artery disease includes controlling things that cause the disease. You cannot control some risk factors. You cannot change your age, gender, ethnic background or family history. However, you can change many of the risk factors for this disease.

Your doctor may suggest the following healthy lifestyle changes:

- Lose excess weight
- Quit smoking
- Exercise regularly
- Control stress
- Decrease fat in your diet
- Limit alcohol consumption

Reducing your risk factors can also have a positive impact on the long-term success of iliac artery disease treatment. Talk to your doctor today about how to increase your chances for a healthier outcome and a more rewarding life with iliac artery disease.